UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

TSCA Inventory Update Reporting Modifications; Proposed Rule	**)**	**DOCKET ID NO. EPA-HQ-OPPT-2009-0187**
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COMMENTS OF THE AMERICAN CHEMISTRY COUNCIL

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American Chemistry Council Comments on
TSCA Inventory Update Reporting Modifications Proposed Rule

EXECUTIVE SUMMARY

The American Chemistry Council (ACC) and its members appreciate the opportunity to comment on the Environmental Protection Agency's (EPA) proposal to amend the Toxic Substances Control Act (TSCA) Inventory Update Rule (IUR).

ACC and its members are committed to enhancing the quantity and quality of data and information provided to EPA on chemicals in commerce. We support the Agency's effort to improve the IUR reporting process and the content of IUR reports. In our view, many elements of EPA's proposal are appropriate enhancements to the TSCA reporting requirements that can inform EPA's assessment of chemicals in commerce and provide useful chemical information to the public.

ACC believes that the proposed IUR amendments provide EPA an opportunity to reinforce how the information will be used, and to what purpose. The IUR information provides an important basis for EPA to screen and prioritize chemicals in commerce for additional review. Augmenting the type and quantity of information as suggested in the proposal could improve the basis for such prioritization decisions, particularly when the IUR information is married to the existing hazard information available to EPA (or has access to) on chemical substances, particularly through voluntary programs such as the High Production Volume (HPV) chemicals program.

The IUR provides the Agency – and the public – important information on chemicals in active commerce, and should provide a more comprehensive picture of chemical manufacturing and use in the United States.

ACC's overriding concerns with the proposed IUR amendments relate to the practical implementation and resulting reliability of the requested information. The lack of sufficient lead time for industry to implement the sweeping changes EPA has proposed could negatively impact the quality of data /information provided to the Agency. EPA surely recognizes that the proposal constitutes the second major revision of IUR reporting requirements in as many reporting cycles. EPA's planned revision schedule does not leave time for industry to prepare for and comply with the proposed modifications for the 2011 IUR. Companies will need sufficient time to address the Agency's planned software tool; change their current reporting systems (often integrated with enterprise-wide software systems); and develop the internal capabilities to collect use and exposure information from marketing and sales groups who are not normally linked into these reporting requirements. Based on industry experience with other Agency-developed reporting software (e.g., the Toxics Release Inventory TRI-ME and ePMN software), both the Agency and the industry will need enough time to ensure that the software operates correctly and can be integrated into company systems. For these reasons, ACC recommends that EPA link the reporting schedule to the final rule's effective date and that EPA announce the extension within the next 60 days.

EPA's proposed five-year "look-back" for the proposed IUR reporting elements is another significant case in point. To date, most company systems have not collected this information in a form readily useable for IUR purposes, for the simple reason that the information was not previously required. A number of companies simply do not track this information, and EPA should acknowledge that the database it is attempting to collect will be incomplete and, at best, of inconsistent quality.

In addition to the points made above, ACC also recommends that:

- EPA should phase in reporting of processing and use information for substances manufactured or imported between 25,000 pounds and 300,000 pounds by partially exempting them from reporting in 2011 (similar to what was done for inorganic chemicals for the 2006 submission);
- EPA should partially exempt the reporting requirement for specified regulated chemicals in 2011, and implement the proposed modification during the next reporting cycle in 2015.

ACC's comments that follow outline a number of concerns and recommendations for improvement in the proposal. We look forward to working with the Agency to craft an IUR reporting system that provides meaningful information and balances both the Agency's need for the information and the practical burden to the regulated community. Some of the issues presented would benefit from further discussion with the Agency. The Agency might want to consider convening an Advisory Panel of stakeholders to address some of the more difficult issues of practical implementation for future IUR reporting, specifically on reporting thresholds for processing and use information and regulated chemicals, complexity of imported mixtures, additional exposure-related data, and processor reporting.

TABLE OF CONTENTS

INTRODUCTION

The American Chemistry Council (ACC) is submitting these comments in response to the proposed modifications to the Toxic Substances Control Act (TSCA) Inventory Update Reporting (IUR) rule. 75 Fed. Reg. 49656 (August 13, 2010). ACC's members are committed to ensuring their chemical products are safe for their intended use. As part of that commitment, we fully recognize industry's responsibility to provide Environmental Protection Agency (EPA) with relevant information necessary to prioritize and assess the risks of chemical substances. ACC agrees that enhancements to the IUR program to obtain appropriate use and exposure information can improve the quality and confidence in the Agency's decisions.

In the detailed comments that follow, ACC recommends specific enhancements to the IUR that we believe are immediately actionable and will provide the data and information needed to improve risk-based decision making by the Agency. We share the Agency's goal of making these changes in the most efficient and cost-effective manner possible.

I. ACC RECOMMENDATIONS FOR SPECIFIC IUR IMPROVEMENTS TO ENHANCE THE QUALITY OF THE IUR DATABASE

ACC supports the Agency's stated goals for the proposed changes to the IUR:

1) Tailor the information collected to better meet the Agency's overall information needs;
2) Increase the ability to effectively provide public access to the information;
3) Obtain new and updated information relating to potential exposures to a subset of chemical substances listed on the TSCA Inventory; and
4) Improve the usefulness of the information reported.[1]

Given the scope of EPA's proposed changes, however, these objectives will be difficult to meet in a single IUR cycle. A more practical approach to the reporting initiative should accommodate the sweeping changes that need to be made in corporate reporting systems, while immediately improving the quality of the information provided to the Agency, and continuing to improve that information over time. ACC recommends that EPA consider the following concepts:

- **Reporting process and use information for chemical substances that are manufactured or imported in volumes of 25,000 pounds per year, with a phased-in reporting scheme for the 2011 reporting cycle.**
    - Substances manufactured or imported at 300,000 pounds or more would be reported within nine to twelve months after implementation of the final rule (to be consistent with the time given during the 2006 IUR reporting);
    - Substances manufactured or imported between 25,000 and 300,000 pounds would be partially exempted from having to report in 2011 and instead would report in the next reporting cycle similar to the inorganic chemicals in 2006 (or at a minimum within twelve months from the initial report); and

[1] See EPA's July 2010 Fact Sheet on Proposed Rule: TSCA Inventory Update Reporting Modifications available at http://www.epa.gov/iur/.

    - Starting with the 2015 reporting cycle, all chemicals over 25,000 would be reported at one time.
- **Reporting annual production or import volumes post-2010**
    - Starting with the 2015 reporting cycle, production and import volumes would be reported for all years since the last principal reporting year, which would result in more accurate information for EPA and more manageable burden for industry.[2]
- **Submission of all IUR reports in an electronic format.**
    - Companies should be encouraged to use electronic submission of IUR reports via the Internet.
    - Alternative submission options (excluding paper) should be available if problems arise with electronic submissions.
    - EPA should provide the ability for industry to upload data via an XML file into the EPA eIUR webtool prior to the start of the submission period. (Detailed discussion of this proposal is included in Section II.C.)
- **EPA's use of other reporting authorities under Section 8 to gather specific details or information on substances not included in the IUR reporting elements.**
    - If there are "for cause" circumstances in which EPA does need specific data/information for its risk assessment work on priority chemicals (especially on downstream uses), it should utilize its other authority under Section 8 to gather those data and information.
- **Increased communication and coordination between Agency and industry on enterprise architecture needs for electronic reporting and submission programs.**

II. CONCERNS WITH CERTAIN PROPOSED MODIFICATIONS

Some of the proposed IUR modifications raise significant concerns, largely around their practical implementation. These include:

- Anticipated reporting schedule for 2011 due to need for additional data/information and electronic reporting
- Industry burden for certain additional reporting requirements:
    1) Requirement for multi-year production and volume reporting for 2006-2009;
    2) Requirement for process and use information for lower volume chemicals;
    3) Requirement for reporting for certain regulated chemicals, regardless of threshold.
- Electronic Reporting Issues
- Changes to Reporting Standard
- Economic Analysis/Burden Estimates
- Expansion of Use Reporting Codes
- Confidential Business Information

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[2] As further outlined in Section III.G, exemptions should be provided for any company engaged in an acquisition or divestiture during the years since the last reporting cycle.

ACC highlights its particular concerns with these items and provides recommended alternatives below.

A. ANTICIPATED REPORTING SCHEDULE FOR 2011

Regardless of what proposed changes are ultimately adopted in a final rulemaking, industry must be given sufficient time to implement those changes. ACC strongly opposes any shortened timeframe for industry reporting that arises because of EPA's delay in proposing these changes and issuing the final IUR rule. Companies are currently engaged in information collection based on what they knew from the 2006 IUR requirements[3]. However, because this proposal has been made eight months into the final collection year, there is considerable uncertainty about what reporting obligations will be made final. Given that the final rule is not expected until sometime in the Spring of 2011 (by EPA's estimates), the current reporting deadline of September 30, 2011 is simply unrealistic.

The problem with reporting schedules is made more complicated because, as with past reporting, the proposed IUR reporting elements are substance-specific. The business of chemistry is product-focused, not substance focused. Marketing data, business units, sales information, computer systems are typically product-focused. The vast majority of chemicals in commerce are not commercialized as individual substances, but as components of chemical products. Thus, EPA's requirement that IUR information be reported on a substance-basis is more difficult than the Agency may appreciate, particularly under the expanded scope of this proposal. That is not to say that information on individual chemical components is not available, but extracting that information requires specific additional computing applications to be applied to the current product-focused-information systems. With product-focused systems currently in place, adequate lead time and extensive efforts are needed to elicit information on the individual substance information in the manner that EPA requires.

ACC member companies have indicated that computer systems can be modified to accomplish the additional information reporting contemplated in the August 2010 proposal. However, companies cannot be expected to invest significant resources in programming based on elements in a proposed rule which could risk wasting valuable resources on uncertain outcomes. Further, once systems are set up, additional time will be needed for system validation. It is extremely unlikely, therefore, that updated systems will be available for use in the 2011 reporting cycle unless the reporting deadline is extended. Those systems could be available for the next IUR reporting cycle, assuming that EPA does not implement further changes to IUR reporting.

[3] EPA appears to have relied on the semi-annual Regulatory Agenda as its primary means to communicate its intent on the rule. The May 2009 Regulatory Agenda noted that expected adjustments were "minor changes to data reporting requirements, possible changes to exemptions for certain chemical substances, and technical corrections." Although the December 2009 Regulatory Agenda indicated a much larger set of changes, it did not adequately identify what EPA ultimately proposed in August 2010.

The reality is many ACC member companies set up their systems based on the 2006 IUR elements, systems that now must be fundamentally reworked. ACC member companies spent thousands of hours developing information systems for the 2006 reporting cycle, and since EPA is again revising the requirements, significant portions of those systems need to be retooled. This takes time. Given the high costs associated with this rulemaking, it is not unreasonable for companies to wait until the final rule is released to be absolutely certain of reporting requirements before implementing expensive procedures needed to comply.

In addition, the proposal to lower the reporting threshold from 300,000 pounds to 25,000 pounds for process and use information will impact a large universe of chemical manufacturers and importers. Many entities potentially impacted by the proposed changes were likely surprised by the reporting obligations that may be forthcoming. Many of these manufacturers and importers are small to medium enterprises. Such companies may not have the ability or resources to set up computer systems that can automatically generate the information for the new reporting elements. Many of these companies did not expect the need to generate these reports and did not allocate staff resources or budget for these activities. They will need sufficient time to familiarize themselves with the newly imposed reporting obligations, begin the process of manually collecting information from the previous ten months, continue data collection through the end of 2010, develop data validation procedures, and generate the information needed for the reports.

It is absolutely imperative that EPA provide sufficient lead time for industry to implement the sweeping changes it has proposed. EPA's planned schedule for a final rule in Spring 2011 does not leave time for industry to prepare for and comply with the proposed modifications for the 2011 IUR. Companies need to be allowed to do it right the first time – to get systems in place; integrate into business units for future reports – without the reporting requirements changing significantly every four years.

ACC notes that EPA proposes to augment the IUR reporting requirements with new reporting software intended to facilitate electronic reporting. We note that in a similar reporting context – the Toxics Release Inventory – full implementation and use of the Agency's TRI-ME reporting software took longer than anticipated. We urge EPA to consider the likelihood of delays or implementation difficulties for the reporting software, and to build those considerations into its implementation schedule.

Accurate data and information must be the ultimate goal of the IUR. A shortened reporting timeframe detracts from that goal and imposes undue and entirely avoidable additional burden on industry. In Unit V.1., EPA recognizes that promulgation of the final rule would be shortly before the next scheduled submission and is considering changing the existing 2011 submission period to another 4-month period later in 2011. For these reasons, ACC strongly recommends that EPA immediately announce its intention to reschedule the 2011 IUR reporting period and confirm that the final reporting period will be tied to the effective date of the final IUR rule. ACC recommends that the first deadline for submission of 2011 IUR reports be due nine to twelve months after the final rule is published. (ACC is also recommending a phased-in reporting schedule for lower production volume substances, as outlined below.) ACC also

requests that the Agency formally announce within 60 days (by December 12, 2011) that the reporting period for the 2011 IUR will be delayed and will end no sooner than nine to twelve months after publication of the final rule.

B. INDUSTRY BURDEN FOR CERTAIN ADDITIONAL REPORTING REQUIREMENTS

The burden associated with several reporting modifications under the proposed IUR will be disproportionately larger than in past years and more far-reaching. In particular, the proposals to include production or import volumes for years prior to the reporting year, to lower the reporting threshold for process and use information, and to remove the reporting threshold for certain regulated chemicals will cause significant increased reporting burdens for industry. While ACC appreciates the Agency's desire for certain information, ACC cautions EPA that it should look closely at its information needs and the data/information that would be submitted. Stakeholders should be assured that the submitted information will be evaluated by EPA in a reasonable timeframe. It will be of little benefit if industry's efforts in submitting information to the Agency results in such a large quantity of data/information that the EPA cannot assess it within a practical amount of time. In addition, it is important that the value to the Agency of the data reported is balanced against the burden for its collection. For these reasons, ACC believes that the Agency should partially exempt reporting of certain proposed IUR changes, as outlined below.

1. <u>EPA Should Drop Proposed Retroactive Reporting for Production Volumes from 2006-2009</u>

As noted above, ACC supports EPA's proposal to include prospective annual production and import volume reporting beginning after the 2011 IUR.[4] ACC is extremely concerned, however, with the timing of EPA's proposal for reporting data from prior years and urges EPA to drop the proposed reporting for 2006 through 2009. This proposed retroactive reporting obligation was completely unexpected and most companies do not presently have systems in place that have captured this information or that can generate it retrospectively. Companies have been preparing for reporting based on 2010 production only and programmed their record keeping and reporting systems for that purpose.

This concern is heightened for imports of mixtures. Some companies may import more than 10,000 materials (some as many as 50,000) per year and up to half of those can be mixtures. Not only will there be difficulties in obtaining and analyzing complex records from import brokers, there will also be problems in locating and retrieving composition data for the mixtures. ACC members estimate that attempting to compile substance import volumes retroactively will increase reporting burden four or five fold, and in some cases may simply not be possible. Note, for example, the issue of substance identity disclosure for past imports from foreign suppliers, as described in our comments on CBI in Section II.G.

[4] August 13, 2010 *Federal Register* notice, Unit III.F.4.

Companies involved in divestitures and acquisitions since 2006 will also have great difficulties in complying with this proposed requirement. It is extremely unlikely that companies in these circumstances will be able to collect all production or import data back through 2006. Historical data are not typically uploaded into systems upon merger/acquisition integration, forcing companies to compile this information manually. And in some instances, acquiring companies do not even receive the historical data from the divesting company.

Compounding the Agency's workload with additional information on four years of retrospective production volume data on every reported chemical is neither practical nor pragmatic. If, for extraordinary circumstances, EPA determines that production volume data are needed on certain chemicals, EPA can compel specific manufacturers and importers to submit such data under EPA's Section 8 authorities.

ACC recommends, therefore, that EPA drop the requirement for retroactive production volume reporting for 2006 through 2009. Instead, EPA should implement the new reporting obligation prospectively, starting in 2011, such that reporting for the years 2011, 2012, 2013, and 2014 will be submitted in the Inventory Update Reporting due in 2015.

2. <u>EPA Should Allow for Phased-In Approach on Reporting of Processing and Use Information</u>

The 2006 IUR involved 6,200 chemicals, of which approximately 3,000 chemicals reported process and use information, over the 300,000 pound threshold. With the lowering of the threshold to 25,000 pounds, it is reasonable to anticipate that the number of chemicals that will be required to report processing and use information will increase two to three-fold. As proposed, this vast amount of information will be submitted all at one time, and EPA staff will need significant time to compile, review, and analyze the data/information. This will be the first reporting cycle with the additional information, and it seems reasonable to anticipate that EPA will need additional time to assess the information submitted.

ACC understands EPA's desire to reduce the process and use reporting threshold from 300,000 per year per facility to 25,000 pounds per year,[5] and agrees with this proposed modification, if it were to be phased in as described above. ACC also needs to understand more fully how such information could be used for prioritization and screening-level characterizations.

[5] Ibid, Unit III.D.2.

EPA should recognize that even without this proposed change, it will be receiving significantly more reporting with the process and use information during the 2011 reporting cycle, as inorganic chemical manufacturers and importers will now be obligated to provide such information. The influx of the inorganic process and use information, coupled with the anticipated significant increase in reports associated with the reporting threshold change, will result in a huge amount of data submitted to EPA at one time.

In addition, this modification will significantly impact small to medium size companies. The lower reporting threshold will also impact many more imported mixtures and impose extreme burden to obtain "reasonably ascertainable" information. As was previously stated, industry needs sufficient lead time to implement the sweeping changes EPA has proposed.

When EPA provided the inorganic chemical sector an exemption from process and use reporting in 2006, the Agency acknowledged the need to allow time for entities new to IUR reporting to become acquainted with the regulations. EPA should provide similar relief to the industry for the first reporting cycle with these proposed changes. Specifically, ACC urges EPA to establish a phased approach for reporting, as outlined below:

- Substances manufactured or imported at 300,000 pounds or more would be reported within nine to twelve months after implementation of the final rule;
- Substances manufactured or imported between 25,000 and 300,000 pounds would be partially exempted from having to report in 2011, and instead would report in the next reporting cycle (or at a minimum within twelve months from the initial report).

Not only will this phased reporting process provide industry with much needed time to compile and report required information on the lower volume chemicals and thereby assure it is high quality information that EPA can rely on, it will allow EPA staff more time to assemble, review and analyze the information as it is submitted in this phased in approach. With experience gained during the first reporting cycle, EPA can proceed with all IUR-reported substances under one deadline in the 2015 cycle.

3. EPA Should Allow for Additional Time for Reporting on Certain Regulated Substances and Consider Establishing a De Minimis Threshold

EPA has proposed to eliminate the 25,000 pound reporting threshold for chemical substances that are subject of a rule promulgated under TSCA Sections 5(a)(2), 5(b)(4), or 6; subject of an order issued under TSCA Sections 5(e) or 5(f), or subject of relief that has been granted under a civil action under TSCA Sections 5 or 7.[6] While ACC supports this proposal in concept, it raises many difficult questions around practical implementation of this requirement. There are approximately 900 chemicals that meet the "regulated substances" criteria. As with the other modified reporting elements, many

[6] Ibid, Unit III.D.3.

companies were not made aware of this change and are unprepared to respond with their information collection processes within the proposed timeframe.

We are now ten months into the information collection year. Companies that manufacture or import these impacted substances in small volumes were not anticipating a reporting requirement, and thus have not been engaged in gathering such information. Trying to pull out this information will be extremely resource-intensive. Further, the utility of collecting such information has not been clearly communicated by EPA. Instead of implementing this new reporting element in 2011, ACC recommends that EPA should convene an Advisory Panel to discuss this proposal further and then implement this modification during the next reporting cycle in 2015. In addition, the Agency should consider a de minimis threshold for reporting of such substances, as described below in our additional comments in Section III.A.9.

C. ELECTRONIC REPORTING ISSUES

ACC supports EPA's proposal to require that all IUR data/information be reported in an electronic format. ACC understands the Agency's frustrations with attempting to enter data from paper copies into the IUR database. Nonetheless, ACC is extremely concerned that the proposal for method of submission[7] provides no alternatives or options to the e-IUR reporting software and CDX submission process. At this time, EPA is still updating the reporting software. Because the final updated version of the software has not been released by EPA, industry has no practical experience with the new system. Our members have not been afforded an opportunity to test the software and verify it is workable with its own varied systems.

In 2006, many ACC member companies attempted to utilize the EPA reporting software but were unable to do so due to numerous and completely unanticipated and thus unavoidable technical difficulties. Precious time and effort were wasted by company staff, and in the end, several companies opted to submit paper records rather than jeopardize their ability to submit reports timely. In addition, the reality is, as EPA is aware, that some ACC members companies and other submitters are having difficulties with the electronic pre-manufacturing notice (E-PMN) system, which is using the same Central Date Exchange (CDX) system proposed for the IUR reporting. Some members report that they have yet to successfully submit an electronic PMN using CDX. Companies are worried about potential liability impacts in 2011 if a failure of the EPA mandated system results in a late submission.

Beyond the potential technical issues associated with electronic reporting, the timing for the eIUR tool will be a major problem. EPA cannot release its eIUR tool until after the final rule is published, and companies will not invest $100,000 to $200,000 in programming costs, which is a fairly conservative estimate, until the rule and eIUR tool are available in final form.

Time will be needed to develop and integrate company data systems with eIUR, as well as time to troubleshoot and interface the company electronic systems with eIUR. For companies effectively to use the system, they will need access to and detailed understanding of EPA's

[7] Ibid, Unit III.B.

system. Until the company system can be integrated with the eIUR system, companies will be forced manually to transcribe information into the eIUR, which will dramatically increase potential for errors.

1. Industry Experience with Past IUR Electronic Reporting

Pre-existing computing system issues result in more manual effort, and therefore more upfront time, being required to collect and aggregate data. For example, many ACC member company computing systems are structured around marketed products. Marketed products are very frequently formulations, instead of the individual chemicals reportable under IUR. Some manual effort (and therefore extra time) is needed to breakdown the volumes of thousands of imported formulations into the aggregated volumes of component substances.

The number of resources to be coordinated, together with the amount of supporting documentation to be cataloged in the event of an audit, requires advance data collection. Data collection for one 2006 IUR-eligible chemical typically involved a team of people across multiple job functions (e.g., regulatory, product stewardship, supply chain, manufacture, industrial hygiene, marketing, sales) and multiple physical locations (e.g., manufacturing site, corporate headquarters, individual business ("division") headquarters). Usually, no one person, one physical site, or one computing application possessed all of the required data for an individual chemical. For this reason, the 2006 IUR submission was a significant undertaking that involved coordinating, for each chemical:

(1) the identification of staff and systems that would possess the required information,
(2) the actual data collection from each of the identified resources along with the eventual collation of the data obtained from the multiple resources,
(3) capturing the data electronically, and finally,
(4) data validation and sign-off.

Capturing the data electronically involved capturing both the supporting information and the actual data values as opposed to the general ranges required on Form U. For example, contrast a spreadsheet showing the calculation of the total number of exposed workers (supporting information) and the exposed worker range reported on Form U (actual data submitted). The supporting information and actual values were recorded for data validation purposes and in the event of a potential audit. There was even more data collection than is visible through a simple tally of the number of substances actually submitted to the Agency, since data collection, validation, and archiving necessary to document why certain manufactured/imported IUR eligible chemical substances were not reported because they did not reach the volume thresholds.

With the expansion of scope of substances requiring Part III use data, the effort for 2010 is estimated to take more resources and time. Also, some data collection is involved to document that a substance did not reach the volume threshold.

2. Proposal to Reduce Industry Burden Associated with 2011 Electronic Reporting

Although ACC appreciates EPA's intent to address problems from the 2006 IUR reporting and with current e-PMN issues, ACC believes EPA must be prepared to offer an alternative reporting

process to companies if these issues are not resolved or if other unexpected technical difficulties associated with the reporting scheme arise.

For ACC member companies to meet the 2011 submission deadline, the data capture process cannot wait until the start of the data submission period, when the eIURweb is expected to be released. To allow companies that need more than the three month window allowed in the proposed rule to collect data, industry is requesting a mechanism for uploading data initially collected outside the EPA eIURweb tool.

ACC proposes, at minimum, the ability to upload data via an XML file into the EPA eIURweb tool with the XML schema published at least three months prior to the start of the submission period. (It is understood that the initial XML schema may undergo small changes over the three months prior to the start of the submission period, and it is requested that these changes be published as made.)

To facilitate preparation of the XML upload file, ACC proposes that validation "lookup" data files from the eIURweb tool also be published at least 3 months prior to the start of the reporting period. This validation data would be supplied to industry in an electronic format such as XML or comma delimited text files. Examples of eIURweb tool validation "lookup" data include:

- Chemical identification data: Chemical Abstracts (CA) Index Name used to list the substance on the public Inventory and the Chemical Abstracts Services (CAS) Registry Number or the TSCA Accession Number for substances on the confidential Inventory (to the extent possible without jeopardizing confidentiality claims);
- Site and company identification data such as Dun and Bradstreet numbers; and,
- EPA codes (e.g., Industrial Function codes) not already published via the instructions manual be published at least three months prior to the start of the reporting period.

ACC also proposes the option for industry to upload a company generated XML file into the e-IURweb software and generate a pre-validation report before final submission of the data through the web. This is analogous to the option in TRI-MEweb to upload an XML file for pre-validation. This would meet the need of larger ACC member companies to collect data in advance to meet the submission deadline and meet EPA's desire that data be run through e-IURweb automated validation checks.

EPA should also make the software downloadable so that companies may enter data and share with other company officers for review and collation prior to submittal. This capability facilitated submissions and reduced errors with the previous IUR software. Some ACC member companies have been advised the new IUR software using CDX will not have this capability.

If impacted ACC member companies are not provided the option to upload a pre-defined XML file into e-IURweb, the data would still need to be collected in advance to meet the submission deadline, but the previously collected data would need to be manually re-keyed into the e-IURweb tool. This would add to the overall burden, since additional staff would need to duplicate previous electronic data capture and re-review for accuracy. Unfortunately, the re-keying of data could lead to typographical errors that cannot be detected by automated validation. For example, a typographical error of a numeric field such as the volume data, if not

caught even on careful human review, would go undetected by automated validation in e-IURweb.

ACC member companies encourage a meeting in 2010 between industry and EPA to review what aspects of tools such as e-PMN and TRI-MEweb were successful and what needs to be changed for consistent reliability to make submissions over the internet successful.

In the event that the eIURweb tool is not functioning at the start of the submission period or technical issues arise making submission problematic, ACC proposes the option for industry to provide the data in XML format submitted via CD or flash drives, instead of the eIURweb tool.

D. CHANGES TO REPORTING STANDARD

ACC does not support EPA's proposal to replace the ``readily obtainable" reporting standard for Part III – Process and Use Information with the ``known to or reasonably ascertainable by" reporting standard.[8] Instead, ACC recommends that EPA provide more specific guidance and strengthen what is expected under the "readily obtainable" information standard.

Many companies believe the "reasonably ascertainable standard" includes in-depth research efforts of company files, literature searches, and possibly surveys of customers, which could be in the thousands. At a recent meeting with ACC, EPA staff specifically noted that on-line research or customer surveys were not expected as part of the reporting standard for Part III information elements. Instead, EPA personnel clarified its expectation that outreach to various company departments would occur as part of the information gathering and that information available within the company would be reported but that customer surveys would not be required. This helpful guidance, which clarifies the level of effort anticipated for reporting process and use, should formally be provided to industry. Changing the reporting standard to "reasonably ascertainable" may result in further confusion among impacted industry regarding EPA's intent.

Companies should not be held to the same reporting standard for marketing information as they are for production/import data. In many cases, manufacturers only have information with their direct customers. Customers associate uses not with individual chemicals substances, but rather with products, many of which are complex mixtures of multiple chemical substances. We recommend that EPA retain and strengthen the "readily obtainable" standard to include use of estimates and best professional judgment.

ACC also takes exception to EPA's stated belief that companies "routinely have more information about how their chemical substances are processed and used"[9] based on industry's experience under the new chemicals program. EPA's reference to the new chemicals program represents a fundamental misunderstanding of the relationship between these reporting programs.

[8] Ibid, Unit III.G.

[9] Ibid.

Pre-manufacture notices (PMNs) report projections of possible or anticipated use scenarios, whereas the IUR requires reporting of factual information as to what has actually occurred in the marketplace. In addition, PMNs reflect the information, expectations, and understanding held by a single submitter (in that there are no customers or downstream users when the PMN is submitted) whereas the IUR requires consideration of what might be happening at downstream companies. Given the fundamental differences between the reporting programs, extrapolating the experience gleaned from the PMN program to anticipate information needs expected under the IUR program is not appropriate. The safe use of chemicals and chemical products is a collective responsibility with manufacturers, distributors, formulators, retail product manufacturers, etc., all having a role.

E. ECONOMIC ANALYSIS/BURDEN ESTIMATES

EPA's economic analysis[10] is not an adequate reflection of the increased burden that will be imposed on industry. ACC believes EPA has significantly underestimated the effort required in collecting, organizing, verifying and reporting IUR data. As previously noted, computer programs need to be designed and implemented (or redesigned and re-implemented). Data from prior years will need to be extricated from records as collection systems had not been established. Personnel will need to be trained. More substances and more data will need to be reported. ACC members estimate that resource requirements for the proposed rulemaking will be four to six times higher than those used in 2006.

ACC strongly disagrees with EPA's reliance on a "per report" basis to determine its burden estimate. This approach ignores time and resources spent on reviewing those chemicals that are not ultimately reported. Unreported chemicals must nonetheless be tracked, calculated, screened, recorded, assessed, aggregated, and screened against reporting thresholds. Indeed, companies assess hundreds of substances that ultimately do not need to be reported. That effort is still part of the overall burden and must be reflected in the total burden estimate.

ACC questions EPA's reliance on 2002 burden survey results in the Economic Analysis. These survey results are simply not reflective of a 2010 national economy, job market, or industry perspective. Indeed, the 2002 IUR reporting scheme did not even include the additional process and use information elements that are a major part of the proposed modifications. ACC members estimate that resource requirements for the proposed rulemaking will be four to six times higher than those expended in the 2006 Inventory Update Reporting.

ACC also questions whether EPA's estimate has been adjusted to include the number of inorganic substance reports that should be added to the baseline. Finally, ACC is concerned with the Agency's use of a twenty-five year amortization period in its Economic Analyses when most regulatory analyses use a ten-year period to analyze costs.

[10] Ibid, Unit VIII.

Complexity of Imported Mixtures

Additionally, EPA's burden estimate clearly demonstrates that the Agency does not appreciate the complexity associated with reporting imported substances, particularly imported mixtures. Below is an overview of actions needed on every single imported product in order to comply with IUR reporting requirements:

a. Imported chemical materials are frequently contained in mixtures, and sometimes complex mixtures. Even raw materials are frequently found in mixtures, and not a single neat substance. The imported raw materials may have an additive package, or may be pre-processed or dispersed in solvents or an aqueous solution mixture. All chemical components in each of these additive packages and solution mixtures must be accounted for.

b. Companies must obtain composition of all products subject to TSCA.
   - The composition must be contemporaneous to the IUR basis year and to the shipment itself. This can be difficult. Product composition can be modified several times in any given year, and changes in composition will impact calculated production volumes.

   - Commerce in chemicals is global. Foreign suppliers must be queried, contacted repeatedly, and negotiations may be required (execution of secrecy agreements) to obtain full composition data for their products, raw materials, and intermediates that a US company purchases.

   - Full composition data for a global company's own products and intermediates that are imported into the US must be obtained by specific importing sites or headquarters.

c. The company will need to set up an information collection system capable of handling large numbers of materials. In some cases, companies may import more than 50,000 materials in a single year.
   - The company must screen out imported materials that are not subject to TSCA (such as FDA-regulated or FIFRA pesticides), screen out article products, and continue processing only those material imports that are subject for consideration in IUR reporting.

d. All imported materials must be broken down by chemical component, and based on the volume of the specific import, the chemical components and their respective weights must be tallied and aggregated with the same chemical volumes coming from other imports.

   - The chemical composition of imported materials can vary from year to year. This means that, if annual and/or retrospective reporting of import data would be reportable to the EPA under a modified IUR reporting scheme, a contemporaneous composition record would have to be established for each year under consideration. These contemporaneous composition data records would be used to break down to

individual chemical substances each product mixture that was imported in a given year. Retention of composition records on a year by year basis is not a current requirement, and many companies only establish such a record for the IUR basis year, which is prior to the reporting year. Thus, obtaining contemporaneous product analyses for imports other than 2010 will not be possible for some companies.

e. The entire annual record of imports (can be tens of thousands of material imports) must be broken down to individual chemical components to arrive at an annual total.

f. After arriving at a grand total of imported volume, per chemical, the company must then determine which chemicals are exempted from IUR reporting (such as naturally occurring substances, or below the reporting threshold, etc.).

g. After arriving at a grand total of imported volume, per IUR reportable chemical, the company must then determine the uses for each reportable substance.

- For example, if a total of 30,000 pounds of ethyl acetate is determined, what were the respective product uses that accounted for those 30,000 pounds? Perhaps 55% was for a consumer automotive product, 30% for an industrial coating, and 15% for a commercial concrete treatment product. Those respective uses will determine what use codes and worker exposure codes need to be provided in Part III of the IUR form.
- To obtain this information, a company must invest significant time and/or system development to look back at the import data once again and determine the specific imported materials that contributed a reportable amount of a specific chemical.

h. The process outlined above applies to EACH imported product. It is a time consuming and burden-intensive process. One ACC company reported 3000 hours of burden for 2006, which covered only 112 substances.

Given the extreme time and resources associated with volume tracking for imported mixtures, which makes up the largest part of the IUR effort, EPA could potentially consider a concentration cut-off (e.g., TSCA Section 12(b) threshold) for imported mixtures whereby importers could eliminate them from consideration due to the relatively low potential they have for exposure (with the exception of chemicals of concern). Another option EPA could consider is allowing reporting of volume ranges or volume estimates for intervening years. This would still provide EPA with relevant information that would help in EPA's desire to track trends, but would allow companies some flexibility in tracking and calculating import volumes.

F. EXPANSION OF USE REPORTING CODES

In its proposed rulemaking, EPA intends to revise the reporting codes for the industrial function categories, the industrial sectors, and the commercial/consumer use categories[11] [12]. ACC

[11] Ibid, Unit III.F.7

[12] Ibid, Unit III.F.8

supports EPA's efforts to improve the quality of use information reported and to harmonize reporting systems between the U.S. and Canada. Nonetheless, EPA should recognize that these changes will result in increased reporting burdens and times, particularly for those companies that had set up electronic information collection systems based on the 2006 reporting elements. Those companies will need to re-map previous use and exposure information to the new use reporting codes. ACC recommends that EPA demonstrate how the old codes map to the new codes in the guidance, and to provide examples for different use categories.

ACC notes that some of the proposed industry sector (IS) codes do not appear to be for TSCA-regulated activities but for FDA-regulated activities. ACC urges EPA to review and address these IS codes.

G. CONFIDENTIAL BUSINESS INFORMATION

ACC supports efforts to reduce the number of unjustifiable CBI claims, but cautions EPA to avoid imposing undue restrictions that would hinder legitimate CBI claims.

ACC supports EPA's commitment to provide disclosure of meaningful, non-CBI health and safety information to the public. As outlined in the proposed rule[13], ACC supports up-front substantiation of claims of confidentiality at the time information is submitted to EPA (including information pertaining to processing and use). Additionally, we support the continued allowance of confidentiality claims for chemical identity for those chemicals listed on the confidential portion of the TSCA inventory, provided the appropriate designations are made.

The proposed rule indicates that where a submitter fails to substantiate the processing and use CBI claim in accordance with the applicable rules, EPA would consider the information not subject to a confidentiality claim and may make the information available to the public without further notice to the submitter. Under TSCA 14(c), when such claims are made, a 30- or 15-day notice is required prior to release, depending on the nature of the information. ACC strongly recommends that EPA ensure that its electronic system notify the submitter within the TSCA designated timeframe that the required information has not been provided. The submitter should have an opportunity to rectify the error before the potentially legitimate CBI claim is disclosed to the public. This approach would be more consistent with the clear intent of Congress in enacting Section 14 (in which CBI information is exempted from mandatory disclosures).[14]

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[13] Ibid, Unit III.H.

[14] The House Committee report included the following discussion:

> In order to insure that the Administrator have full and complete access to information relevant to achieving the objectives of the bill, H.R. 14032 gives the Administrator broad information gathering authority. However, **the Committee recognizes that some information which the Administrator may obtain will be of tremendous competitive value to the person providing it**. Accordingly, section 14 contains specific prohibitions against release of such information so that the competitive position of those supplying the information will be protected.

EPA has long recognized that confidential business information, including chemical identities, can have significant economic value. For example, in compiling the Inventory, EPA chose to publish only generic names for chemical substances whose identities were confidential business information ("CBI") so as to protect that economic value.[15] In doing so, it explained that it "had to balance the competing concerns of section 14 and sections 8(a) and 5(b)" because

> ... there is no doubt that the fact that certain substances are manufactured or processed for commercial purposes would be confidential under traditional trade secrets law and case law under the Freedom of Information Act fourth exemption (5 U.S.C. 552(b) (4)).[16]

EPA has proposed to amend Section 711.15(b)(3)(i)(A), which requires suppliers of materials with identities claimed CBI to provide chemicals identity information jointly to EPA using e-IUR web and CDX. This is a particularly troubling issue for reporting activities on imports, especially imports from the 2006-2009 period. Most companies currently have no contractual language in place requiring foreign suppliers to agree to provide confidential identity information, much less agreements to provide that information in an electronic format. In the absence of enforceable contractual requirements to provide this information, ACC believes it will be difficult to compel foreign suppliers to provide such information for past purchases.

ACC supports EPA's proposal to prohibit claims of confidentiality pertaining to the designation that information is not "not readily obtainable" and ``known to or reasonably ascertainable by" the submitter.

III. ACC INPUT ON EPA'S REQUEST FOR COMMENTS

In addition to the comments listed above, ACC is providing comments on the specific issues raised in Units III and V of the August 13, 2010, *Federal Register* notice.[17]. This input is provided in order of appearance in the *Federal Register* and should not be construed as an indication of ACC priority. Further, some of these comments reiterate points made in Sections I and II above and reference those sections where appropriate.

> H.R. Rep. No. 1341, 94th Cong., 2d Sess. (1976) ("House Rep.") at 49-50, Legis. Hist. at 456-57 (emphasis added).

[15] 40 C.F.R. § 710.7(f)(1), 42 Fed. Reg. 64572, 64579 (Dec. 23, 1977).

[16] 42 Fed. Reg. at 64590 (comment 93).

[17] ACC requested an extension of the comment period to be able to address in greater detail the implications of the suggestions and questions raised by the Agency. Unfortunately, the Agency declined that request. Some of those elements might, if included in the final rule, significantly change the scope and burden of the rule. ACC encourages the Agency to consider soliciting additional public comment if the scope of the IUR rule changes on the basis of these specific issues.

A. MODIFICATION AFFECTING ALL MANUFACTURERS (INCLUDING IMPORTERS) – UNIT III

1. DELETING SUPERFLUOUS TEXT ASSOCIATED WITH REPORTING PRODUCTION VOLUMES

ACC does not support EPA's proposal to delete the phrase "provided that the reported figures are within +/- 10% of the actual volume."[18] We do not agree with EPA's statement that this phrase is superfluous since companies report calculated data rather than actual data in the IUR and because any number reported accurately to two significant figures is within 10% of the correct value. This statement gives the impression that the proposed revision only removes redundancy and imposes no change in the requirement. However, reporting accurately to two significant figures is <u>not</u> equivalent to reporting to a precision of +/- 10%. While it is true that two values that are the same to two significant digits are always within <u>no more than</u> 10% of each other, reporting to two significant figures alone can require much greater precision than the current +/- 10% standard. For example, actual values that would round to the two significant digits 11 and 10 differ by approx. 10% (1/10), but actual values that round to 99 and 98 differ by only about 1% (1/98). **The required precision inherent in the revised language, therefore, is a sliding scale that is <u>arbitrarily</u> dependent on the specific digits involved.** If the value that must be reported to two significant digits is 99,000 lbs. the required precision is approximately 1%, whereas if a value reported to two significant digits is 110,000 lbs. the allowed precision is approximately 10%.

The current IUR language recognizing a +/-10% standard of precision has been part of the IUR regulations since their inception in 1986. This current language implies recognition that there is some level of inherent and unavoidable imprecision in any number reported, and that no measurement can be made with absolute precision. For example, substance volumes for imported mixtures must always be calculated based on the reported composition of the mixture. Production data recorded in gallons would need to be converted to pounds to meet IUR reporting requirements. Each measurement, calculation, and conversion has an associated imprecision. As a practical matter for IUR reporting, pounds produced is often a calculated value, not a direct measurement, and may be calculated using two or more equally valid approaches. While each approach may not give exactly the same value, the values should be considered to be equivalent if they are within 10% of each other. The +/- 10% precision language adopted in the 1986 regulation is reasonable. A sliding standard for precision based solely on two significant digits is not an appropriate approach to reporting data under the IUR. The current language should not be changed.

[18] August 13, 2010 *Federal Register* notice, Unit III.A.5.

2. REQUIRE ELECTRONIC SUBMISSIONS OVER THE INTERNET

EPA proposed to require electronic submission over the Internet[19], and asked for input as to whether there will be circumstances in which a company may not have Internet access to report IUR data electronically. ACC does not believe that to be the case for its members. However, we are not sure whether all foreign suppliers have access to the Internet for joint submissions. This type of situation, in which Internet access may not be accessible, further supports ACC's recommendation that EPA have an alternative option for electronic submission process.

3. ELECTRONIC SIGNATURE PROCESS

In response to EPA's request for feedback on the proposed electronic signature process,[20] ACC believes there will be circumstances in which reporting sites will need to designate more than one individual for the ESA and EPA's system should accommodate this need. Although it is unlikely that a technical contact at a production site would be engaged in PMN submissions (as this typically occurs at company headquarters), it is still a reasonable approach to set up the process that would allow for more than one authorized official.

ACC notes that the staff that generates and submits the IUR reports are seldom company officers. As such, the eIUR system needs to have a section that separately identifies the responsible party/signatory and the submitter/technical contact. ACC is also concerned that eIUR has capability for only one Authorized Official (AO). Companies need the capability to have two Authorized Officials (AOs), one at the IUR coordinator level and one at the senior leader signature/approval level.

EPA will also need to address issues that may arise when foreign suppliers register with CDX.

4. DEFINITION OF "MANUFACTURE"

EPA has proposed to amend the definition of "manufacture" to add language concerning extraction of a previously existing substance[21]. ACC believes the proposed language is overly broad and confusing. The proposed definition should be revised to more precisely articulate what are, and are not, IUR-reportable activities. As currently proposed, the definition seems to imply that activities such as simple purification of a chemical mixture (without any chemical synthesis) could fall within the definition of "manufacture".

[19] Ibid, Unit III.B.2.

[20] Ibid, Unit III.B.3.

[21] Ibid, Unit III.C.1.

When assessing substances for IUR reportability, those responsible for TSCA compliance at a chemical plant typically will focus their evaluation on substances formed as a result of a chemical reaction, whether the substance is the intended reaction product, an isolated intermediate, or a byproduct used or offered for a non-exempt commercial purpose. That is, the focus of these assessments is the chemical transformation of one or more chemical substances into another chemical substance. Compliance with TSCA dictates that the site must assure that all such chemically synthesized substances are in compliance with the requirements of TSCA Section 5, and this same knowledge is leveraged for evaluation of IUR-eligibility.

Conversely, when Section 5 and IUR status of a substance has been confirmed, further processing operations that involve only physical separation or purification of a substance in which the chemical identity of the substance does not change would not typically be the focus of further IUR evaluation at a chemical manufacturing site. However, the proposed language "…extraction…of a component chemical substance from a previously existing chemical substance or a complex combination of chemical substances" could be interpreted to encompass, for example, the distillation of a reaction solvent for reuse in the process. If such a solvent does not undergo any chemical change, but only becomes contaminated during the reaction process, its "extraction" away from other substances in the mixture should not constitute "manufacture" of the solvent. We do not believe it is the Agency's intent to treat such separation of the existing solvent from this mixture to be reported in the IUR, but the revised definition of "manufacture" could imply this is the case.

The broad and ambiguous definition proposed would require EPA to provide extensive explanation and clearer guidance than is currently available. In fact Question and Answer 8 in the draft EPA document "Q&A DOCUMENT: Recycling and the TSCA Inventory of Chemical Substances Premanufacture Notification and Inventory Update Reporting Requirements" provides an example that appears similar to the solvent recycling described above, but EPA's guidance states that the solvents in the Q&A example are IUR-reportable. It is not obvious from the Q&A example what would be factually different from that example and the solvent recycling scenario noted above. Modification of this example, and additional examples exemplifying these differences, would be essential.

On the other hand, if the Agency does intend for each such physical separation step in a chemical process to constitute "manufacture", this would be a profound change in reporting requirements. In the scenario noted above, the same solvent molecule could be "manufactured" numerous times without any change in its chemical identity. Such an expansion in the scope of the definition of "manufacture" would constitute a very substantial change in reporting requirements and burden. Essentially, every chemical process with a recycling step would need re-evaluation in light of this change.

The impetus for this proposed change to the definition of "manufacture" appears to be an attempt to clarify the requirements for reporting of byproducts, not to impose a new

standard for reporting of an existing substance solely because it is isolated or "extracted" from a mixture. Because of the complexity of the byproduct issue, the requirements would be better addressed by more specific and detailed language in the regulation targeted to byproducts, rather than by the addition of the broad and confusing modification to the definition of "manufacture" that has been proposed.

ACC disagrees with EPA's proposal that in toll manufacturing situations, the primary reporting responsibility is on the contracting company. Instead, ACC believes that the two parties should be jointly responsible, with the toll manufacturer completing Parts I and II and the contracting company completing Part III.

5. DEFINITION OF SITE

ACC does not support the definition for "site" [22] because it does not properly account for situations where multiple companies are co-located at the same site (*i.e.,* occupying a contiguous property). In this case the companies should be allowed to report separately.

ACC believes the definition provided for "site" is likely sufficient to address unique circumstances such as portable manufacturing units. ACC notes that unless EPA engages in active and aggressive outreach to stakeholders that might be engaged in portable manufacturing, it is unlikely that those parties will recognize the need to report under this statute. For the most part, those entities do not view themselves as "chemical manufacturers" and may not, without significant EPA outreach and education, understand reporting obligations apply to them.

6. COMMERCIAL VS. CONSUMER USE

ACC members do not oppose the changes in commercial or consumer use codes[23] but ACC requests further distinctions between commercial and consumer uses.

7. METHOD FOR DETERMINING WHETHER A PERSON IS SUBJECT TO IUR REPORTING REQUIREMENTS

ACC believes EPA's proposal for determining whether a person is subject to IUR reporting requirements based on production volumes over 25,000 pounds in one year [24] is appropriate. As noted in EPA's proposal, the determination of reporting would be based on production volumes on those years prior to the reporting year, but that actual process and use data would be reported for the information collection year (*e.g.,* the year immediately prior to the reporting year). This change should apply to all chemicals, and could be implemented for the 2015 reporting cycle.

[22] Ibid, Unit III.C.2.

[23] Ibid, Unit III.C.4

[24] Ibid, Unit III.D.1

The final rule should make clear that a company does not need to report for a given chemical substance if they no longer produce or import it in the principal year due to divestiture, business discontinuance, etc. Likewise, if a substance reaches the 25,000 threshold in one year, but the company ceases production or import in the principal reporting year, the company should not be obligated to report.

8. ELIMINATE 300,000 LB. THRESHOLD FOR PROCESSING AND USE INFORMATION

ACC supports the proposed reduction of the process and use reporting threshold to 25,000 pounds[25]. As previously stated, however, ACC proposes that substances manufactured or imported between 25,000 and 300,000 pounds be partially exempted from having to report in 2011 and instead report in the next reporting cycle.

ACC does not support a lower reporting threshold, such as the 10,000 pound volume, outlined in Unit V of the *Federal Registe*r notice.

9. ELIMINATION OF THE 25,000 LB. THRESHOLD FOR CERTAIN REGULATED CHEMICAL SUBSTANCES

As noted, ACC can support in principle the proposal to eliminate reporting volume thresholds for those chemicals that are the subject of a rule proposed under TSCA section 5(a)(2), 5(b)(4), or 6, [26] but implementation of this requirement poses serious practical issues and therefore should be deferred until 2015. Importers, for example, would have great difficulty in knowing that low-concentration ingredients are present in formulated mixtures, especially when they are not subject to inclusion on a label or MSDS (<1%). This is an issue that would benefit from further discussion with the Agency.

If EPA were to proceed with this requirement in 2015, ACC urges EPA to establish a *de minimis* production volume threshold for these chemicals to avoid excessive industry burden to monitor and report on use information for minimal volumes of chemicals that will not provide much useful information to the Agency. ACC recommends a *de minimis* threshold of 2,500 pounds, which is 10% of the proposed reporting threshold of 25,000 pounds. The 2,500 pound *de minimis* is also similar to the *de minimis* level in the European Union REACH regulations.

Should there be extraordinary circumstances where the Agency does need information on these smaller volumes, it has the option to compel the production of such information under TSCA Section 8 authorities.

[25] Ibid, Unit III.D.2

[26] Ibid, Unit III.D.3.

In the instructions for the 2006 IUR, EPA provided an appendix with the list of "Inventory Chemical Substances Subject to Proposed or Final TSCA Rules or Orders." There were 913 chemicals on the list that met the proposed criteria for elimination of the 25,000 pound reporting threshold. The updated list for 2011 would be longer and would include more chemicals subject to proposed rules. EPA should provide a specific list of all the regulated substances that would be impacted by this change.

ACC notes that EPA should clarify that this modification will not impact new chemical polymers and microorganisms that are subject to TSCA Section 5(e) consent orders or significant new use rules (SNURs). These materials are otherwise generally exempted from the IUR requirements. In fact, the notice specifically states that polymers are "fully exempt from reporting." Given the text in the modification, however, some parties may be confused unless EPA clarifies this point.

10. TECHNICAL CONTACTS

In response to EPA's proposals on technical contacts for Form U[27], as previously stated, ACC believes EPA should establish a procedure that allows the option for more than one technical contact per report. In addition, it is not necessary to have the Technical Contact located at each reporting site. Starting with the 2006 IUR, the scope of data collected broadened beyond information from just plant site resources. Many ACC member companies relied on a corporate contact to coordinate the 2006 data collection effort. Though not located at the submitting plant site, this corporate contact was listed as the technical contact because (1) he/she kept a record of who provided what data, (2) his/her job function involved understanding the context of any data requests from the Agency (e.g., prevent a miscommunications if a volume request is viewed in terms of a product, instead of in terms of an IUR reported chemical by company resources), and (3) his/her job function was to ensure adequate record keeping and follow up with the Agency.

Using one central contact as a coordinator of IUR data submissions may be analogous to the EPA New Chemicals Notice Management Branch staff that coordinate review of PMN submissions and negotiations with submitters on Section 5 Consent Orders. ACC member companies appreciate the Agency's ability to run their process efficiently. This efficiency would be negatively impacted if EPA provided to a PMN submitter the names of multiple Agency resource contacts without coordinating through the EPA New Chemicals Notice Management Branch staff. Many ACC member companies request the option to provide just one, potentially off site, IUR technical contact.

ACC members support EPA's contention that the technical contact would be most effective if it were an employee of the submitting company.

[27] Ibid, Unit III.F.2.

11. CHEMICAL IDENTITY/CHEMICAL NAME

EPA is proposing to remove the PMN number as an allowed chemical identifying number[28]. ACC is concerned that for historical products, this may pose an extra burden for both industry and EPA. Manufacturers would need to go to EPA to request the accession numbers and EPA would need an established process and designated contact for these types of inquiries. As an alternative, EPA could provide a table of PMN numbers with associated TSCA accession numbers, so companies could find the needed data without inquiries to EPA.

ACC notes that some members encountered problems with selecting the chemical identity from the list generated by EPA itself. These problems will need to be rectified prior to the next reporting cycle.

ACC supports the proposed procedure outlined in the proposal for joint submissions.

12. PRODUCTION VOLUME – REPORT PRODUCTION VOLUME FOR EACH OF THE YEARS SINCE THE LAST PRINCIPAL REPORTING YEAR

ACC supports periodic reporting of production volume for each of the years since the last principal reporting year[29] starting in 2015. As already noted in Section II, ACC strongly opposes imposition of this reporting requirement in 2011, as it will require retroactive review and reporting for past years. Such reporting will result in unnecessarily excessive industry burden, entirely disproportionate to any value added to EPA.

ACC believes that in the event a company is engaged in an acquisition or divestiture during the years since the last reporting cycle, it should only be obligated to report for the time period in which it actually owned the business.

ACC would strongly oppose any proposal to include additional reporting elements beyond production or import volumes during the years since the last principal reporting year.

13. PRODUCTION VOLUME - VOLUME OF CHEMICAL SUBSTANCE USED ON-SITE

EPA is proposing to require that submitters report the volume of a manufactured (or imported) chemical that is used at the reporting site[30]. This reporting requirement would replace the requirement to indicate that the chemical is site-limited. ACC believes more

[28] Ibid, Unit III.F.3.i.

[29] Ibid, Unit III.F.4.i.

[30] Ibid, Unit III.F.4.ii.

clarification is needed as to whether this reporting obligation applies only to products that are reacted out or if it also applies to articles.

14. PRODUCTION VOLUME – INDICATE WHETHER IMPORTED CHEMICAL SUBSTANCES ARE PHYSICALLY AT REPORTING SITE

EPA has proposed to require submitter to indicate if imported chemicals are physically located at the reporting site.[31] As EPA has already acknowledged, imported chemicals are not typically physically located at the reporting site, which is usually the company headquarters. We question the need and utility for this information. It provides no relevant information for use in risk screening purposes.

15. REPORT VOLUME EXPORTED

ACC does not support EPA's proposal to require reporting of export volumes for the 2011 IUR cycle[32]. Systems are in place to capture volumes of manufactured and imported chemicals, but are not in place to accurately capture the volume of all of the chemicals contained in exported finished products.

If EPA provided additional details as to how this information is needed for risk screening purpose, this reporting element might make sense for future IUR primary reporting years. Rather than a separate reporting code in Part II, ACC suggests that EPA consider an option in which export volumes are reported as a use code in Part III. This approach better reflects how information is stored and accessible in company computer programs

16. IDENTIFY WHETHER A CHEMICAL SUBSTANCE IS TO BE RECYCLED, REMANUFACTURED, REPROCESSED, REUSED, OR REWORKED

ACC does not believe the reporting element to identify whether a chemical is to be recycled, remanufactured, reprocessed, reused or reworked will be useful as currently written.[33] EPA's objective for this reporting is unclear, and additional guidance is needed.

As previously noted in Section III.D., ACC believes that EPA's attempt to address reporting requirements for byproducts may be interpreted as a new standard for reporting of an existing substance solely because it is isolated or "extracted" from a mixture. It should not include substances whose chemical identity doesn't change. Because of the complexity of the byproduct issue, EPA needs to provide more specific and detailed

[31] Ibid, Unit III.F.4.iii.

[32] Ibid, Unit III.F.4.iv.

[33] Ibid, Unit III.F.5.

language in the regulation and associated guidance documents focused on byproduct reporting.

17. CONSUMER AND COMMERCIAL USE REPORTING – NUMBER OF COMMERCIAL WORKERS REASONABLY LIKELY TO BE EXPOSED

ACC does not believe chemical companies will be able to provide accurate estimate of the number of workers per commercial sector and urges EPA to drop this element from the proposal[34]. As acknowledged by EPA, chemical manufacturers or importers do not have sufficient information about the work practices of eventual commercial users to estimate number of exposed workers. The manufacturer of a substance may be several levels removed from the formulator and the seller of a commercial-use product containing that chemical. Rather than including this as a reporting element on Form U, EPA should rely on worker statistics from the Bureau of Labor as it conducts risk assessments, or gather additional data under a separate section 8(a) rule.

18. CHANGES TO STANDARD FOR THE REPORTING OF PROCESSING AND USE INFORMATION (REPLACE THE "READILY OBTAINABLE" REPORTING STANDARD WITH THE "KNOWN TO OR REASONABLY ASCERTAINABLE BY" REPORTING STANDARD)

As previously noted in section II.D. above, ACC does not believe that EPA's proposal to change the reporting standard for processing and use information[35] is necessary, based on recent input from EPA staff. Instead, ACC urges EPA to issue more detailed guidance on what the Agency expects related to internal company efforts in information collection practices, to include use of estimates and best professional judgment.

19. UPFRONT SUBSTANTIATION OF PROCESSING AND USE INFORMATION CBI CLAIMS

ACC does not support all of EPA's proposals for upfront substantiation on processing and use information.[36] In particular, market share and percentage of production volume is considered proprietary information and should not be subject to upfront substantiation.

[34] Ibid, Unit III.F.8.iii.

[35] Ibid, Unit III.G.

[36] Ibid, Unit III.H.2

20. AMENDMENTS TO REQUIREMENTS CONCERNING CBI - LIMITATION ON CONFIDENTIALITY CLAIMS FOR DATA ELEMENTS IDENTIFIED AS ``NOT KNOWN OR REASONABLY ASCERTAINABLE''

ACC can support EPA's proposal to limit CBI claims on data elements identified as "not readily obtainable' or "not reasonably ascertainable."[37].

21. MODIFICATIONS SPECIFICALLY AFFECTING IMPORTERS

ACC believes that more guidance is needed for EPA's proposed joint reporting procedures[38]. ACC is concerned that there are numerous opportunities for problems to arise in the electronic reporting procedures outlined in EPA's proposal.

22. CHANGE TO REPORTING FREQUENCY

ACC believes the reporting frequency of five years is appropriate, but is willing to support EPA's proposal to change to a four-year cycle[39]. ACC does not believe that shorter intervals are necessary, particularly with the proposed reporting of production volumes for in-between years. Annual reporting would present challenges to both EPA and industry, and the processing and use information does not change much over time. With every new cycle of IUR reporting, EPA would need to update its findings to reflect the new data.

Should extraordinary circumstances arise in which EPA needs data in between reporting cycles, it can exercise its information collection authorities under TSCA Section 8.

23. EXPLANATION OF BYPRODUCT REPORTING

ACC notes that EPA's explanation of byproduct reporting[40] continues to be confusing to many stakeholders. As highlighted in the proposal notice, many companies may not consider themselves as manufacturers of chemical substances that are subject to reporting under IUR.

As previously noted in Section III.D., ACC believes that EPA's attempt to address reporting requirements for byproducts may be interpreted as a new standard for reporting of an existing substance solely because it is isolated or "extracted" from a mixture. Because of the complexity of the byproduct issue, EPA needs to provide more specific

[37] Ibid, Unit III.H.3.

[38] Ibid, Unit III.I.

[39] Ibid, Unit III.J.

[40] Ibid, Unit IV.B.

and detailed language in the regulation and associated guidance documents focused on byproduct reporting.

B. REQUEST FOR FURTHER COMMENTS – UNIT V

1. TRANSITION TO NEW IUR REQUIREMENTS

As previously outlined in Section II.A, ACC strongly opposes any shortened timeframe for industry reporting that arises because of EPA's delay in proposing its changes and commensurate delay in issuing the rule in final. EPA must provide sufficient time for impacted companies to get information collections systems in place to gather the required information; to become accustomed to the new electronic reporting systems proposed; and to engage in other activities related to the new reporting elements. EPA's apparent rush for information in order to meet the pre-established submission period of June 1 – September 30, 2011, will also negatively impact the quality of data it receives.

In Section II, ACC identified several specific recommendations for transition, including timing for 2011 reporting schedule, reporting for 2006-2009 production/volume information, and phasing in reporting of processing and use information for substances manufactured between 25,000 and 300,000 pounds. This is an issue that would benefit from further discussion with the Agency.

2. USE OF IUR DATA TO SUPPORT EPA FOCUS ON EXISTING CHEMICALS THAT POSE UNREASONABLE RISKS

ACC supports EPA's stated intent to increase its emphasis to assess, prioritize, and take action on existing chemicals that may pose unreasonable risks[41]. ACC had been supportive of EPA's Chemical Assessment and Management Program (ChAMP) in which the Agency utilized existing data on hazard and exposure to complete screening level risk assessments. It is important for the Agency to indicate how the additional IUR data will be utilized in its Enhanced Chemicals Management Program or individual Chemical Action Plans. The IUR process should be used as a screening tool for prioritization of chemicals in commerce. This is an issue that would benefit from further discussion with the Agency.

After each reporting cycle, EPA should issue a summary of IUR data, similar to the December 2008 report "2006 Inventory Update Reporting: Data Summary." That report should include specific details on how EPA is and will be using the IUR data in EPA programs.

ACC appreciates EPA's acknowledgement that it should avoid gathering information which EPA may not be able to use. To avoid this situation, EPA should phase-in reporting requirements for the next cycle of reporting, as the Agency will not be in a

[41] Ibid, Unit V.2.

position to fully assess and evaluate all the information elements currently included in the EPA proposal.

3. IUR EXEMPTIONS

ACC supports EPA's intent to include chemical substances that are the subject of Section 4, 5(a)(2), 5(b)(4) or 6 proposed or promulgated rules in the list of exclusions[42]. If chemicals that would typically be exempted from reporting are subject to TSCA Section 4, 5(a)(2), 5(b)(4) or 6 testing, the exemptions from reporting should be lifted and the chemical should be reported. ACC believes this process is more reasonable than removing the substances from the reporting exemptions list.

As new information and technologies arise, ACC believes that circumstances will develop in which additional reporting exemptions will need to be considered. For this reason, ACC supports the ability for EPA to add new exclusions to reporting exemptions as appropriate. This clearly supports the Agency's intent to avoid gathering information which EPA may not need.

4a. REPORTING FREQUENCY

ACC believes a reporting frequency of four or five years is reasonable and appropriate. EPA's suggestion that an annual reporting system is needed to analyze trends[43] is unnecessary and would impose excessive reporting obligations on industry. With submission of production and import volumes in intervening years per EPA's proposal, EPA will have relevant information to analyze trends in volumes. ACC does not believe that significant changes in use patterns will occur from year to year and thus, detailed process and use information on an annual basis is not necessary for EPA's evaluation effort, and will certainly cause unnecessary burden to industry. If certain circumstances arise, EPA can use its authorities under Section 8 to gather additional information in between IUR reporting deadlines.

In addition, ACC has serious concerns that EPA will not be able to adequately compile, assess, and evaluate all the information elements currently proposed within a one year period.

EPA speculates that annual reporting would allow integration of IUR reporting with the already-required annual TRI reporting. ACC questions this and questions why, if true, EPA has not pursued opportunities to integrate the programs during the IUR reporting years. To date, EPA has never attempted to do so.

[42] Ibid, Unit V.3.

[43] Ibid, Unit V. 4 i-ii

4b. REPORTING THRESHOLD

ACC strongly opposes any proposal to lower the reporting threshold below 25,000 pounds. EPA's suggestion that lowering the threshold to the 2002 threshold of 10,000 pounds[44] is a return to status quo is incorrect. In 2002, there were no requirements for additional process and use information, there were no additional requirements for protecting confidential business information, and the entire IUR program was completely different. If EPA reaches a point where it is interested in evaluating chemicals at lower production volumes, it can use its authorities under TSCA Section 8 to collect such information.

5. PROPOSED INFORMATION COLLECTION VERSUS PROPER AGENCY FUNCTION PERFORMANCE

EPA asks for feedback on whether the proposed information collection is sufficient for proper Agency function performance[45]. ACC notes that it is difficult to provide useful feedback because EPA has not provided any specific input on its plans for using the information collected under the IUR. EPA should clearly indicate how the IUR data will be utilized in its Enhanced Chemicals Management Program or individual Chemical Action Plans or similar program that systematically reviews hazard and exposure of existing chemicals. Without such input, it is difficult for ACC to judge the practical utility of the proposed reporting elements for Agency functions.

ACC recognizes that exposure information elements are critical for chemical prioritization and risk assessment purposes, and therefore, has been supportive of EPA's efforts to collect such information. The Agency must develop and publicly share its plans for a risk evaluation program that systematically prioritizes and evaluates existing chemicals.

6. BURDEN ESTIMATE

ACC does not believe EPA's economic analysis is an adequate reflection of the enormous burden that will imposed on industry[46]. ACC's analysis of EPA's estimated burden estimate is included in Section II.E.

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[44] Ibid, V.4.iii

[45] Ibid, Unit V.5.

[46] Ibid, Unit V.6.

7. FURTHER MODIFICATIONS TO ENHANCE INFORMATION COLLECTED

In these comments, ACC has identified numerous areas in which EPA can modify its proposal to enhance information collection, including but not limited to:

a. Information reporting threshold: EPA should clarify its guidance related to collection of information related to processing and use. Agency staff has indicated that EPA's intent is for thorough review of company files and input of various company personnel.

b. Use and function: EPA needs to carefully clarify whether reported use and function codes apply to the use and function of the reported substance in a downstream product, or the use and function of the product itself.

c. Identification of whether a substance is recycled, remanufactured, reprocessed, reused or reworked.

8. TECHNOLOGY OPTIONS TO MINIMIZE BURDEN ON INFORMATION COLLECTION

ACC supports EPA's proposal to utilize technology options to minimize burdens.[47] However, as clearly outlined in Section II.C, ACC is extremely concerned that the proposal provides no alternatives or options to the e-IUR reporting software and CDX submission process. This issue must be addressed prior to finalization of the rulemaking.

9. ADDITIONAL EXPOSURE-RELATED DATA SIMILAR TO SECTION 5 REPORTING

EPA's proposal to require exposure-related data similar to those elements included in Section 5 reporting is inappropriate.[48] EPA's reference to the new chemicals program represents a fundamental misunderstanding of the relationship between these reporting programs. Premanufacture notices (PMNs) report projections of possible or anticipated use scenarios, whereas the IUR requires reporting of factual information as to what has actually occurred in the marketplace. In addition, PMNs reflect the information, expectations, and understanding held by a single submitter (in that there are no customers or downstream users when the PMN is submitted) whereas the IUR requires consideration of what might be happening at downstream companies. Given the fundamental differences between the reporting programs, extrapolating the experience gleaned from the PMN program to anticipate information needs expected under the IUR program is not appropriate.

Providing manufacturing and use diagrams for IUR reporting for all chemicals would be extremely problematic. In many circumstances, processes are not static for any given

[47] Ibid, V.8.

[48] Ibid, V.9.

manufactured product, depending on the different customers and their needs. In addition, with emphasis on continuous improvement, companies may adjust processes several times in a given year. So one reported substance could have multiple processes associated with it. In addition, process information is considered proprietary information.

If circumstances arise in which EPA needs data not reportable under the IUR program, it can utilize its authorities under Section 8 to require that information. The IUR process should primarily be viewed as a screening tool for prioritization of chemicals in commerce, not as a source of all information for all chemical management purposes. This is an issue that would benefit from further discussion with the Agency.

10. PROCESSOR REPORTING

ACC agrees with EPA's assertion that processors may be more familiar with downstream use and exposure potentials for certain chemicals. Including processors in the IUR reporting cycle as EPA proposes,[49] however, will further complicate an already cumbersome program. It will also further increase burden to many ACC member companies, which may also process substances in addition to manufacture or import. It will result in a significant increase in reports and data, which EPA may not be equipped to assess and evaluate. Rather than requiring upfront reporting by processors, EPA should utilize its authorities under Section 8 to gather and tailor that information when needed on targeted chemicals, separate from and subsequent to the IUR reporting process. This is an issue that would benefit from further discussion with the Agency.

CONCLUSION

We appreciate this opportunity to submit these comments on the IUR proposal. ACC remains committed to enhancing the quantity and quality of data provided to EPA on chemicals in commerce. As noted, we support the Agency's effort to improve the IUR reporting process and the content of IUR reports. The concerns raised in these comments are primarily focused on timing and practicality issues. We urge EPA to carefully consider these issues and work with industry to address them in a reasonable manner. In addition to the other recommendations included in these comments, ACC also suggests that EPA form an Advisory Panel among interested stakeholders to discuss future IUR reporting, industry burdens and further opportunities for improvement.

[49] Ibid, V.10.